IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

PURDUE PHARMACEUTICAL PRODUCTS L.P., *et al.*, Plaintiffs, v. ACTAVIS ELIZABETH LLC, *et al.*, Defendants.	**Consolidated Civil Action No. 12-CV-05311 (JLL)(JAD)**

AMENDED JOINT CLAIM CONSTRUCTION AND PREHEARING STATEMENT

Pursuant to Paragraph 13 of the Superseding Amended Pretrial Scheduling Order (docket entry 71), the order changing the deadline for the parties to file their joint claim construction statement (docket entry 87), and Local Patent Rule 4.3, Plaintiffs Purdue Pharmaceutical Products L.P.; Purdue Pharma L.P.; and Transcept Pharmaceuticals, Inc. (collectively, "Plaintiffs"); and Defendants Actavis Elizabeth LLC; Novel Laboratories, Inc.; Par Formulations Private Ltd. and Par Pharmaceutical, Inc.; and Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. (collectively, "Defendants") hereby submit their Amended Joint Claim Construction and Prehearing Statement concerning U.S. Patent No. 7,682,628 ("'628 Patent"); U.S. Patent No. 8,242,131 ("'131 Patent"); and U.S. Patent No. 8,252,809 ("'809 Patent").

I. Construction of Claim Terms on which the Parties Agree (L. Pat. R. 4.3(a))

In accordance with Local Patent Rule 4.3(a), the parties agree that the terms below should be construed as follows:

U.S. Patent No. 7,682,628

Term Identified for Construction	Joint Proposed Construction
"insomnia" (Claim 1)	"a sleep disorder characterized by symptoms including, without limitation, difficulty in falling asleep, difficulty in staying asleep, intermittent wakefulness, and/or waking up too early"
"dissolves" (Claims 1, 3, and 4)	"reduces from a solid form to a liquid form"
"average plasma concentration" (Claim 14)	"mean peak plasma concentration within about 5 minutes to about 2 hours"

U.S. Patent No. 8,242,131

Term Identified for Construction	Joint Proposed Construction
"middle-of-the-night insomnia" (Claims 1 and 12)	"the condition wherein a subject, after falling asleep, awakens and has difficulty returning to sleep"
[Preamble] "A method of treating middle-of-the-night insomnia in a [non-elderly][elderly] patient without prophylactically administering zolpidem, comprising" (Claims 1 and 12)	The preamble in Claims 1 and 12 is limiting.

U.S. Patent No. 8,252,809

Term Identified for Construction	Joint Proposed Construction
"MOTN insomnia" (Claims 1 and 12)	"middle-of-the-night insomnia, which is the condition wherein a subject, after falling asleep, awakens and has difficulty returning to sleep"

"an amount sufficient to produce a plasma concentration between about 25 ng/ml and about 50 ng/ml within 20 minutes of administration, when evaluated in an appropriate patient population" (Claims 1 and 12)	Plain and ordinary meaning.
"[the solid unit dosage form] dissolves" (Claims 13–16)	In Claims 13 and 15: "a portion of the solid unit dosage form converts to a solution or slurry form" In Claims 14 and 16: "the solid unit dosage form converts to a solution or slurry form"

II. Proposed Constructions of Disputed Claim Terms (L. Pat. R. 4.3(b))

In accordance with Local Patent Rule 4.3(b), each party's proposed construction for the disputed claim terms is as follows:

U.S. Patent No. 7,682,628

Term Identified for Construction	Plaintiffs' Proposed Construction	Defendants' Proposed Construction
"buffer" (Claim 1)	Plain and ordinary meaning. To the extent additional construction is necessary: "at least one substance used to maintain an approximate pH range"	"A buffer system of two or more buffering agents."

U.S. Patent No. 8,242,131

Term Identified for Construction	Plaintiffs' Proposed Construction	Defendants' Proposed Construction
"without prophylactically administering zolpidem" (Claims 1 and 12)	"without delivering zolpidem into the patient's body before the initial onset of sleep"	Plain and ordinary meaning.

"without residual sedative effects" (Claims 1 and 12)	"with no or minimal subjective feelings of sedation, as evaluated by: (a) testing acceptably in at least one test exploring psychomotor performance, attention, information processing, and memory used by those of skill in the art; and/or (b) demonstrating plasma levels of zolpidem, at an appropriate time point, below about 20 ng/ml"	The term is indefinite.

U.S. Patent No. 8,252,809

Term Identified for Construction	Plaintiffs' Proposed Construction	Defendants' Proposed Construction
[Preamble] "A solid unit dosage composition for the treatment of MOTN insomnia, said composition comprising" (Claims 1 and 12)	The preamble in Claims 1 and 12 is limiting.	The preamble in Claims 1 and 12 is not limiting.
"effective amount of zolpidem" (Claims 1 and 12)	"amount of zolpidem that is capable of achieving a therapeutic effect in a subject in need thereof"	Defined by the claims. Claim 1: "an amount of less than $1.30x10^{-5}$ moles of zolpidem, and is an amount sufficient to produce a plasma concentration between about 25 ng/ml and about 50 ng/ml without 20 minutes of administration." Claim 12: "0.5 to 4.75 mg of zolpidem hemitartrate, and is an amount sufficient to produce a plasma concentration between about 25 ng/ml and about 50 ng/ml within 20 minutes of administration."

Term Identified for Construction	Plaintiffs' Proposed Construction	Defendants' Proposed Construction
"buffering agent" (Claim 12)	Plain and ordinary meaning. To the extent additional construction is necessary: "substance used to maintain an approximate pH range"	"A weak acid or weak base that changes the pH of saliva."
"binary buffer system" (Claims 5, 6, 22, and 23)	Plain and ordinary meaning. To the extent additional construction is necessary: "system used to maintain an approximate pH range comprising at least one proton-donating component and at least one proton-accepting component"	"Two buffering agents."
"quick-dissolving tablet" (Claims 7 and 24)	Plain and ordinary meaning. To the extent additional construction is necessary: "tablet formulated to dissolve in a subject's mouth within about 6 minutes"	"one that completely dissolves in the mouth in less than about 6 minutes."

As required by Local Patent Rule 4.3(b), Exhibit A provides Plaintiffs' proposed constructions for each of these terms and identifies the intrinsic and extrinsic evidence on which Plaintiffs intend to rely to support their proposed constructions or to oppose Defendants' proposed constructions.

As required by Local Patent Rule 4.3(b), Exhibit B provides Defendants' proposed constructions for each of these terms and identifies the intrinsic and extrinsic evidence on which Defendants intend to rely to support their proposed constructions or to oppose Plaintiffs' proposed constructions.

III. Significant or Dispositive Claim Terms (L. Pat. R. 4.3(c))

Local Patent Rule 4.3(c) requires the parties to identify the terms whose construction will be most significant to the resolution of the case and any disputed terms whose construction will be case or claim dispositive or substantially conducive to promoting settlement.

In accordance with Local Patent Rule 4.3(c), Plaintiffs believe that the following terms may be more significant to the resolution of the case than the other disputed terms: "buffer" (Claim 1 of the '628 Patent); and "without residual sedative effects" (Claims 1 and 12 of the '131 Patent).

In addition to the aforementioned terms, Defendants believe that the following terms may be significant to the resolution of the case: "buffering agent" (Claim 12 of the '809 Patent); and "binary buffer system" (Claims 5, 6, 22, and 23 of the '809 Patent).

IV. Anticipated Time Needed for the Claim Construction Hearing (L. Pat. R. 4.3(d))

In accordance with Local Patent Rule 4.3(d), the parties estimate that the claim construction hearing will require approximately 4 hours, divided equally between Plaintiffs (2 hours) and Defendants (2 hours).

V. Identification of Witnesses for the Claim Construction Hearing (L. Pat. R. 4.3(e))

The parties anticipate presenting their claim construction arguments at the hearing through counsel only (and have based their 4-hour time estimate set forth above in Section IV on this assumption).

Dated: September 19, 2013

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EXHIBIT A

U.S. Patent No. 7,682,628 ("'628 Patent")

Term Identified for Construction	Plaintiffs' Proposed Construction	Evidence that May Be Used to Support Plaintiffs' Construction and/or Oppose Defendants' Construction
"buffer" (Claims 1 and 9)	Plain and ordinary meaning. To the extent additional construction is necessary: "at least one substance used to maintain an approximate pH range"	**Specification and Prosecution History:** The '628 Patent: Claims 1 and 9; Abstract; col. 2, l. 42–col. 3, l. 26; col. 3, ll. 30–35; col. 7, ll. 15–58; col. 14, l. 64–col. 15, l. 3; col. 18, l. 57–col. 19, l. 20; col. 21, ll. 27–37; col. 22, ll. 24–64; col. 43, ll. 2–17; col. 44, ll. 18–43. Provisional Application No. 60/608,957: pages 14–16; Claims 54 and 63. '628 prosecution history: Original Application, Claims 1 and 16; Applicant's October 17, 2008 Amendment and Response; Applicant's Feb. 24, 2009 Amendment and Response; Applicant's August 14, 2009 Amendment and Response. U.S. Patent No. 7,658,945: Claim 1. **Extrinsic Evidence:** The United States Pharmacopeia (2004), at 2671, 2724–25 (PIZ00055310–14) Oxford Dictionary of Biochemistry and Molecular Biology (2000), at 83 (PIZ00055297–99) Plaintiffs believe that this term should be given its plain and ordinary meaning and does not require additional construction

Term Identified for Construction	Plaintiffs' Proposed Construction	Evidence that May Be Used to Support Plaintiffs' Construction and/or Oppose Defendants' Construction
		or extrinsic evidence. However, Plaintiffs reserve the right to introduce and rely on expert testimony from Dr. James E. Polli to support their position and to oppose Defendants' proposed construction, on one or more of the following subjects: background on drug formulations; the definition of a person of ordinary skill in the art; and how one of ordinary skill in the art would understand the term "buffer." Dr. Polli may also respond to opinions rendered by Defendants' expert(s).

U.S. Patent No. 8,242,131 ("'131 Patent")

Term Identified for Construction	Plaintiffs' Proposed Construction	Evidence that May Be Used to Support Plaintiffs' Construction and/or Oppose Defendants' Construction
"without prophylactically administering zolpidem" (Claims 1 and 12)	"without delivering zolpidem into the patient's body before the initial onset of sleep"	**Specification and Prosecution History:** The '131 Patent: Claims 1 and 12; col. 1, ll. 32–49; col. 28, l. 54–col. 29, l. 3. '131 prosecution history: Applicant's January 13, 2010 Amendment and Response; Applicant's October 1, 2010 Amendment and Response. **Extrinsic Evidence:** Teitelbaum, J., *From Fatigued to Fantastic: A proven program to regain vibrant health, based on a new scientific study showing effective treatment for chronic fatigue and fibromyalgia*, at 115–116 (2001) (JNTDEF0005429–32) Zammit, G., *Sleep and Residual Sedation After Administration of Zaleplon, Zolpidem, and Placebo During Middle-of-the-Night Awakening*, J. Sleep. Med. 2(4):417 at 417 (2006) (JNTDEF0000830–36) As further support for their construction, Plaintiffs may also rely on the testimony of Dr. Meir Kryger on one or more of the following subjects: background on sleep medicine and hypnotics; the definition of a person of ordinary skill in the art; and how one of ordinary skill in the art would understand the term "without prophylactically administering zolpidem." Dr. Kryger may also respond to opinions rendered by Defendants' expert(s).

Term Identified for Construction	Plaintiffs' Proposed Construction	Evidence that May Be Used to Support Plaintiffs' Construction and/or Oppose Defendants' Construction
"without residual sedative effects" (Claims 1 and 12)	"with no or minimal subjective feelings of sedation, as evaluated by: (a) testing acceptably in at least one test exploring psychomotor performance, attention, information processing, and memory used by those of skill in the art; and/or (b) demonstrating plasma levels of zolpidem, at an appropriate time point, below about 20 ng/ml"	**Specification and Prosecution History:** The '131 Patent: Claims 1 and 12; col. 4, ll. 26–39; col. 6, ll. 41–42; col. 6, l. 42–col. 7, l. 16; col. 7, ll. 37–49; col. 30, ll. 27–34; col. 33, ll. 3–7. **Extrinsic Evidence:** Danjou, P. et al., *A comparison of the residual effects of zaleplon and zolpidem following administration 5 to 2 h before awakening*, BR. J. Clin. Pharmacol, 48:367–374 (1999), at abstract, 358, 368–69, 372 (JNTDEF0003916–23) Doghramji, K., *The Need for Flexibility in Dosing of Hypnotic Agents*, 23 SLEEP, Suppl. 1, S16–22 (2000), at S19 (JNTDEF0000168–74) Hindmarch, I. et al., *Comparison of the residual effects of zaleplon and zolpidem after administration during the night*, European Neuropsychopharmacology, vol. 10, Suppl. 3, S107–S394 (2000) at S394 (JNTDEF0000273–75) Hindmarch, I. et al., *Residual effects of zaleplon and zolpidem following middle of the night administration five hours to one hour before awakening*, Hum. Psychopharmacol. Clin. Exp., 16: 150–167 (2001), at 159–65 (JNTDEF0000276–85) Hindmarch, I. et al., *A double-blind, placebo-controlled investigation of the residual psychomotor and cognitive effects of zolpidem-MR in healthy elderly volunteers*, Br. J. Clin. Pharmacol., 62:5, 538–45 (2006), at 538–39, 542–43 (PIZ00055435–42)

Term Identified for Construction	Plaintiffs' Proposed Construction	Evidence that May Be Used to Support Plaintiffs' Construction and/or Oppose Defendants' Construction
		Holm, K. *Zolpidem: An update of its pharmacology, therapeutic efficacy, and tolerability in the treatment of insomnia*, Drugs, 59(4), 865–889 (2000) at abstract, 869–72 (JNTDEF0004046–70) Lader, M. et al., *A Double-Blind Study to Establish the Residual Effects of Zopliclone on Performance in Healthy Volunteers*, Pharmacology 27: suppl. 2, 98–108 (1983), at 98, 100, 107 (PIZ00055604–17) Muraoka, M. et al., *Residual Effects of Repeated Administration of Triazolam and Nitrazepam in Healthy Volunteers*, Neuropsychobiology, 25:134–139 (1992), at 134–35, 138–39 (PIZ00055618–26) O'Hanlon, J., *Residual Effects on Memory and Psychomotor Performance of Zaleplon and Other Hypnotic Drugs*, J. Clin. Psychiatry, Vol. 4 (suppl 1), 38–44 (2002), at 38–43 (PIZ00055627–35) Stone, B. et al., *Noise-induced sleep maintenance insomnia: hypnotic and residual effects of zaleplon*, Br. J. Clin. Pharmacol., 53, 196–202 (2002), at 196, 198–99, 201 (PIZ00055636–42) Subhan, Z. et al., The Effects of Lormetazepam on Aspects of Sleep and Early Morning Performance, Eur. J. Clin. Pharmacol., 25:47–51 (1983) , at 47–50 (PIZ00055643–50) Verster, J. et al., *Residual Effects of Middle-of-the-Night Administration of Zaleplon and Zolpidem on Driving Ability, Memory Functions, and Psychomotor Performance*, 22 J Clin Psychopharmacol., no. 6, at 576–583 (2002) , at 576, 578–82 (JNTDEF0005287–03) Walsh J. K. et al., *Lack of Residual Sedation Following Middle-of-the-Night Zaleplon Administration in Sleep Maintenance Insomnia*, Clinical Neuropharmacology, Vol. 3, No. 1, 17–21 (2001), at 17, 19–21 (JNTDEF0005304–08)

Term Identified for Construction	Plaintiffs' Proposed Construction	Evidence that May Be Used to Support Plaintiffs' Construction and/or Oppose Defendants' Construction
		Zammit, G. et al., *The Importance of Residual Effects When Choosing a Hypnotic: The Unique Profile of Zolpidem*, J. Clin. Psychiatry, Vol. 3(2), 53–60 (2001), at 53, 57–59 (PIZ00055667–76) As further support for their construction, Plaintiffs may also rely on the testimony of Dr. Meir Kryger on one or more of the following subjects: background on sleep medicine and hypnotics; the definition of a person of ordinary skill in the art; and how one of ordinary skill in the art would understand the term "without residual sedative effects." Dr. Kryger may also respond to opinions rendered by Defendants' expert(s).

U.S. Patent No. 8,252,809 ("'809 Patent")

Term Identified for Construction	Plaintiffs' Proposed Construction	Evidence that May Be Used to Support Plaintiffs' Construction and/or Oppose Defendants' Construction
[Preamble] "A solid unit dosage composition for the treatment of MOTN insomnia, said composition comprising" (Claims 1 and 12)	The preamble in Claims 1 and 12 is limiting.	**Specification and Prosecution History:** The '809 Patent: Claims 1, 12, 13–16; Abstract; col. 1, ll. 66–67, ll. 43–62; col. 4, l. 57–col. 5, l. 3; col. 6, ll. 48–61; col. 7, l. 48–col. 8, l. 13; col. 29, ll. 17–56; col. 31, l. 64–col. 32, l. 2. '809 prosecution history: Examiner's March 12, 2012 Office Action; Examiner's July 18, 2012 Notice of Allowability; '131 prosecution history: Applicant's October 1, 2010 Amendment and Response; Examiner's July 13, 2009 Office Action; Examiner's April 22, 2010 Office Action; Examiner's May 19, 2011 Notice of Allowability; Examiner's July 5, 2012 Notice of Allowability. **Extrinsic Evidence:** As further support for their construction, Plaintiffs may also rely on the testimony of Dr. Meir Kryger on one or more of the following subjects: background on sleep medicine; the definition of a person of ordinary skill in the art; and how one of ordinary skill in the art would understand the preamble to be limiting. Dr. Kryger may also respond to opinions rendered by Defendants' expert(s).

Term Identified for Construction	Plaintiffs' Proposed Construction	Evidence that May Be Used to Support Plaintiffs' Construction and/or Oppose Defendants' Construction
"effective amount of zolpidem" (Claims 1 and 12)	"amount of zolpidem that is capable of achieving a therapeutic effect in a subject in need thereof"	**Specification and Prosecution History:** The '809 Patent: Claims 1 and 12; col. 7, l. 48–col. 8, l. 13. '131 prosecution history: Applicant's January 13, 2010 Amendment and Response. **Extrinsic Evidence:** Holm, K. *Zolpidem: An update of its pharmacology, therapeutic efficacy, and tolerability in the treatment of insomnia*, Drugs, 59(4): 865–889 (2000) at abstract, 873–77 (JNTDEF0004046-70) Stone, B. et al., *Noise-induced sleep maintenance insomnia: hypnotic and residual effects of zaleplon*, Br. J. Clin. Pharmacol., 53, 196–202 (2002), at 196–97, 200 (PIZ00055636–42) Tsutsui. S. and Zolpidem Study Group, *A Double-Blind Comparative Study of Zolpidem versus Zopiclone in the Treatment of Chronic Primary Insomnia*, Journal of International Medical Research, 29: 163 (2001), at 166–71, 173–74 (PIZ00055651–66) Zammit, G. et al., *The Importance of Residual Effects When Choosing a Hypnotic: The Unique Profile of Zolpidem*, J. Clin. Psychiatry, Vol. 3(2), 53–60 (2001), at 53, 55 (PIZ00055667–76) As further support for their construction, Plaintiffs may also rely on the testimony of Dr. Meir Kryger on one or more of the following subjects: background on sleep medicine; the definition of a person of ordinary skill in the art; and how one of ordinary skill in the art would understand the term "effective amount of zolpidem." Dr. Kryger may also respond to opinions rendered by Defendants' expert(s).

Term Identified for Construction	Plaintiffs' Proposed Construction	Evidence that May Be Used to Support Plaintiffs' Construction and/or Oppose Defendants' Construction
"buffering agent" (Claim 12)	Plain and ordinary meaning. To the extent additional construction is necessary: "substance used to maintain an approximate pH range"	**Specification and Prosecution History:** The '809 Patent: Claim 12; col. 28, ll. 1–18. **Extrinsic Evidence:** The United States Pharmacopeia (2004), at 2671, 2724–25 (PIZ00055310–14) Oxford Dictionary of Biochemistry and Molecular Biology (2000), at 83 (PIZ00055297–99) Plaintiffs believe that this term should be given its plain and ordinary meaning and does not require additional construction or extrinsic evidence. However, Plaintiffs reserve the right to introduce and rely on expert testimony from Dr. James E. Polli to support their position and to oppose Defendants' proposed construction, on one or more of the following subjects: background on drug formulations; the definition of a person of ordinary skill in the art; and how one of ordinary skill in the art would understand the term "buffering agent." Dr. Polli may also respond to opinions rendered by Defendants' expert(s).

Term Identified for Construction	Plaintiffs' Proposed Construction	Evidence that May Be Used to Support Plaintiffs' Construction and/or Oppose Defendants' Construction
"binary buffer system" (Claims 5, 6, 22, and 23)	Plain and ordinary meaning. To the extent additional construction is necessary: "system used to maintain an approximate pH range comprising at least one proton-donating component and at least one proton-accepting component"	**Specification and Prosecution History:** The '809 Patent: Claims 5, 6, 22, and 23; col. 2, ll. 27–54; col. 3, l. 50–col. 4, l. 7; col. 5, ll. 59–67; col. 9, ll. 32–45; col. 10, l. 53–col. 11, l. 3; col. 11, ll. 42–55; col. 12, ll. 40–51; col. 13, ll. 1–61; col. 14, ll. 21–35; col. 15, ll. 16–25; col. 16, ll. 17–29; col. 26, l. 62–col. 27, l. 21; col. 28, ll. 37–48. '809 prosecution history: Examiner's January 10, 2012 Office Action; Examiner's August 18, 2011 Office Action. **Extrinsic Evidence:** Plaintiffs believe that this term should be given its plain and ordinary meaning and does not require additional construction or extrinsic evidence. However, Plaintiffs reserve the right to introduce and rely on expert testimony from Dr. James E. Polli to support their position and to oppose Defendants' proposed construction, on one or more of the following subjects: background on drug formulations; the definition of a person of ordinary skill in the art; and how one of ordinary skill in the art would understand the term "binary buffer system." Dr. Polli may also respond to opinions rendered by Defendants' expert(s).

Term Identified for Construction	Plaintiffs' Proposed Construction	Evidence that May Be Used to Support Plaintiffs' Construction and/or Oppose Defendants' Construction
"quick-dissolving tablet" (Claims 7 and 24)	Plain and ordinary meaning. To the extent additional construction is necessary: "tablet formulated to dissolve in a subject's mouth within about 6 minutes"	**Specification and Prosecution History:** The '809 Patent: Claims 7 and 24; col. 9, ll. 50–58; col. 10, ll. 46–60; col. 11, 21–28, 56–64; col. 12, ll. 14–21; col. 13, ll. 4–13, ll. 38–43; col. 14, ll. 36–39; col. 15, ll. 39–44; col. 17, ll. 30–39; col. 21, l. 64–col. 22, l. 16; col. 26, ll. 50–61; col. 28, ll. 37–48; col. 29, ll. 4–13, 48–56; Tables 1 and 2 and their descriptions in col. 25–26. **Extrinsic Evidence:** Plaintiffs believe that this term should be given its plain and ordinary meaning and does not require additional construction or extrinsic evidence. However, Plaintiffs reserve the right to introduce and rely on expert testimony from Dr. James E. Polli to support their position and to oppose Defendants' proposed construction, on one or more of the following subjects: background on drug formulations; the definition of a person of ordinary skill in the art; and how one of ordinary skill in the art would understand the term "quick-dissolving tablet." Dr. Polli may also respond to opinions rendered by Defendants' expert(s).

EXHIBIT B

U.S. Patent No. 7,682,628 ("the '628 Patent")

Term Identified for Construction	Defendants' Proposed Construction	Evidence that May Be Used to Support Defendants' Construction and/or Oppose Defendants' Construction
"buffer" (Claims 1 and 9)	"A buffer system of two or more buffering agents."	Abstract Col. 2, l. 42 - col. 3, l. 45 Col. 3, l. 46 – col. 5, l. 7 Col. 7, l. 61 – col. 10, l. 50 Col. 11, ll. 8-63 Col. 12, ll. 16-63 Col. 13, l. 4 – col. 13, l. 45 Col. 13, l. 65 – col. 14, l. 44 Col. 14, l. 63 – col. 15, l. 64 Col. 16, ll. 20-30 Col. 18, l. 57 - col. 23, l. 25 Col. 23, l. 51 – col. 24, l. 3 Col. 26, ll. 13-37 Col. 28, ll. 8-30 Col. 28, l. 65 – col. 29, l. 17 Col. 33, ll. 29-40 The Examples in the '628 patent '323 Application, August 3, 2007, Original Application '323 application, October 17, 2008 Amendment and Response June 21, 2008 Declaration of Nilesh H. Parikh, PHD filed October 17, 2008 '323 application, January 27, 2009 Office Action '323 application, February 24, 2009 Amendment and Response Under 37 C.F.R. 1.116 '323 application, May 28, 2009 Office Action '323 application, August 14, 2009 Amendment and Response '323 application, August 5, 2009 Declaration of Nikhilesh Singh, PHD filed August 14, 2009 '641 application (application for USPN 7,658,945), June 21, 2008 Declaration of Nilesh H. Parikh, PHD filed June 30, 2008

Term Identified for Construction	Defendants' Proposed Construction	Evidence that May Be Used to Support Defendants' Construction and/or Oppose Defendants' Construction
		'641 application, June 30, 2008 Amendment and Response '641 application, October 20, 2008 Office Action '641 application, November 3, 2008 Interview Summary (date of interview: October 30, 2008) '641 application, November 4, 2008 Amendment and Response Under 37 C.F.R. 1.116 '641 application, February 20, 2009 Office Action '641 application, August 5, 2009 Declaration of Nikhilesh Singh, PHD filed August 20, 2009 '641 application, August 20, 2009 Amendment and Response HAWLEY'S CONDENSED CHEMICAL DICTIONARY 169 (13TH Ed./revised by Richard J. Lewis, Sr. 1997) U.S. Patent No. 5,527,817 U.S. Patent No. 6,200,604 U.S. Patent No. 8,252,809 U.S. Patent Appl. Pub. No. 2003/0008005 In Exhibit A hereof, Plaintiffs reserve the right to introduce and rely on expert testimony from Dr. James E. Polli to support their position and to oppose Defendants' proposed construction, on one or more of the following subjects: background on drug formulations; the definition of a person of ordinary skill in the art; and how one of ordinary skill in the art would understand the term "buffer." Defendants maintain that in making such designation Plaintiffs have failed to comply with the requirements of L. Pat. R. 4.2(b), which requires not only an identification of experts who will provide extrinsic evidence in support of claim construction positions, but also a description of the substance of any such expert's proposed testimony. Plaintiffs have failed to provide any such substantive description, and therefore have failed to meet the requirements of L. Pat. R. 4.2(b). As a result, Defendants object to the introduction of expert testimony by Plaintiffs as to claim

Term Identified for Construction	Defendants' Proposed Construction	Evidence that May Be Used to Support Defendants' Construction and/or Oppose Defendants' Construction
		construction. However, should Plaintiffs introduce the aforementioned expert testimony, Defendants reserve the right to introduce and rely on expert testimony from Dr. Bozena Michniak-Kohn to rebut such expert testimony.

U.S. Patent No. 8,242,131 ("the '131 Patent")

Term Identified for Construction	Defendants' Proposed Construction	Evidence that May Be Used to Support Defendants' Construction and/or Oppose Defendants' Construction
"without prophylactically administering zolpidem" (Claims 1 and 12)	Plain and ordinary meaning.	Col. 1, ll. 32-49; Col. 28, l.54-col. 29, l. 3. In Exhibit A hereto, Plaintiffs state they may rely on the testimony of Dr. Meir Kryger on one or more of the following subjects: background on sleep medicine and hypnotics; the definition of a person of ordinary skill in the art; and how one of ordinary skill in the art would understand the term "without prophylactically administering zolpidem." Defendants maintain that in making such designation Plaintiffs have failed to comply with the requirements of L. Pat. R. 4.2(b), which requires not only an identification of experts who will provide extrinsic evidence in support of claim construction positions, but also a description of the substance of any such expert's proposed testimony. Plaintiffs have failed to provide any such substantive description, and therefore have failed to meet the requirements of L. Pat. R. 4.2(b). As a result, Defendants object to the introduction of expert testimony by Plaintiffs as to claim construction. However, should Plaintiffs introduce the aforementioned expert testimony, Defendants reserve the right to introduce and rely on expert testimony from Dr. John W. Winkelman to rebut such expert testimony.
"without residual sedative	This term is indefinite.	In Exhibit A hereto, Plaintiffs state they may rely on the testimony of Dr. Meir Kryger on one or more of the following

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effects" (Claims 1 and 12)		subjects: background on sleep medicine and hypnotics; the definition of a person of ordinary skill in the art; and how one of ordinary skill in the art would understand the term "without residual sedative effects." Defendants maintain that in making such designation Plaintiffs have failed to comply with the requirements of L. Pat. R. 4.2(b), which requires not only an identification of experts who will provide extrinsic evidence in support of claim construction positions, but also a description of the substance of any such expert's proposed testimony. Plaintiffs have failed to provide any such substantive description, and therefore have failed to meet the requirements of L. Pat. R. 4.2(b). As a result, Defendants object to the introduction of expert testimony by Plaintiffs as to claim construction. However, should Plaintiffs introduce the aforementioned expert testimony, Defendants reserve the right to introduce and rely on expert testimony from Dr. John W. Winkelman to rebut such expert testimony.

U.S. Patent No. 8,252,809 ("the '809 Patent")

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"effective amount of zolpidem" (Claims 1 and 12)	Defined by the claims. Claim 1: "an amount of less than $1.30x10^{-5}$ moles of zolpidem, and is an amount sufficient to produce a plasma concentration between about 25 ng/ml and about 50 ng/ml without 20 minutes of administration." Claim 12: "0.5 to 4.75 mg of zolpidem hemitartrate, and is an amount sufficient to produce a plasma concentration between about 25 ng/ml and about 50 ng/ml within 20 minutes of administration."	Col. 43, lns. 5-9 Col. 43, ln. 43-Col. 44, ln. 1 In Exhibit A hereof, Plaintiffs state they may rely on the testimony of Dr. Meir Kryger on one or more of the following subjects: background on sleep medicine; the definition of a person of ordinary skill in the art; and how one of ordinary skill in the art would understand the term "effective amount of zolpidem." Defendants maintain that in making such designation Plaintiffs have failed to comply with the requirements of L. Pat. R. 4.2(b), which requires not only an identification of experts who will provide extrinsic evidence in support of claim construction positions, but also a description of the substance of any such expert's proposed testimony. Plaintiffs have failed to provide any such substantive description, and therefore have failed to meet the requirements of L. Pat. R. 4.2(b). As a result, Defendants object to the introduction of expert testimony by Plaintiffs as to claim construction. However, should Plaintiffs introduce the aforementioned expert testimony, Defendants reserve the right to introduce and rely on expert testimony from Dr. John W. Winkelman to rebut such expert testimony.
"buffering agent" (Claim 12)	"A weak acid or weak base that changes the pH of saliva."	Col. 2, ll. 26-53 Col. 3, l. 26 - col. 4, l-7 Col. 5, ll. 38-67 Col. 8, ll. 46-54 Col. 9, ll. 32-45 Col. 10, l. 53 - col. 11, l. 3 Col. 11, l. 36- col. 12, l. 4 Col. 12, ll. 22-51 and 61-67 Col. 13, ll. 4-24 and 38-61

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		Col. 14, ll. 21-51 Col. 15, ll. 16-67 Col. 16, ll.17-67 Col. 19, l. 50 – col. 20, l. 6 Col. 21, ll. 18-32 and 43-636 Col. 22, ll.31-50 Col. 23, ll.10 – 33 Col. 23, l. 54 – col. 24, l 9 Col. 24, ll. 25-44 Col. 26, ll. 28 and 34 (phosphate buffer) Col. 26, l. 62 – col. 27, l. 21 Col. 27, ll. 59-65 Col. 28, ll. 1-18 and 37-48 Col. 29, ll. 48-56. HAWLEY'S CONDENSED CHEMICAL DICTIONARY 169 (13TH Ed./revised by Richard J. Lewis, Sr. 1997) U.S. Patent No. 7,658,945 U.S. Patent No. 7,682,628 U.S. Patent No. 5,527,817 U.S. Patent No. 6,200,604 U.S. Patent Appl. Pub. No. 2003/0008005 '323 application, October 17, 2008 Amendment and Response '323 application, June 21, 2008 Declaration of Nilesh H. Parikh, PHD filed October 17, 2008 '323 application, January 27, 2009 Office Action '323 application, February 24, 2009 Amendment and Response Under 37 C.F.R. 1.116 '323 application, May 28, 2009 Office Action '323 application, August 14, 2009 Amendment and Response '323 application, August 5, 2009 Declaration of Nikhilesh Singh, PHD filed August 14, 2009 '641 application (application for USPN 7,658,945), June 21,

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		2008 Declaration of Nilesh H. Parikh, PHD filed June 30, 2008 '641 application, June 30, 2008 Amendment and Response '641 application, October 20, 2008 Office Action '641 application, November 3, 2008 Interview Summary (date of interview: October 30, 2008) '641 application, November 4, 2008 Amendment and Response Under 37 C.F.R. 1.116 '641 application, February 20, 2009 Office Action '641 application, August 5, 2009 Declaration of Nikhilesh Singh, PHD filed August 20, 2009 '641 application, August 20, 2009 Amendment and Response In Exhibit A hereof, Plaintiffs reserve the right to introduce and rely on expert testimony from Dr. James E. Polli to support their position and to oppose Defendants' proposed construction, on one or more of the following subjects: background on drug formulations; the definition of a person of ordinary skill in the art; and how one of ordinary skill in the art would understand the term "buffering agent." Defendants maintain that in making such designation Plaintiffs have failed to comply with the requirements of L. Pat. R. 4.2(b), which requires not only an identification of experts who will provide extrinsic evidence in support of claim construction positions, but also a description of the substance of any such expert's proposed testimony. Plaintiffs have failed to provide any such substantive description, and therefore have failed to meet the requirements of L. Pat. R. 4.2(b). As a result, Defendants object to the introduction of expert testimony by Plaintiffs as to claim construction. However, should Plaintiffs introduce the aforementioned expert testimony, Defendants reserve the right to introduce and rely on expert testimony from Dr. Bozena Michniak-Kohn to rebut such expert testimony.
		Col. 2, ll. 26-53

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"binary buffer system" (Claims 5, 6, 22, and 23)	"Two buffering agents."	Col. 3, l. 26 - col. 4, l-7 Col. 5, ll. 38-67 Col. 8, ll. 46-54 Col. 9, ll. 32-45 Col. 10, l. 53 – col.11, l. 3 Col. 11, l. 36- col. 12, l. 4 Col. 12, ll. 22-51 and 61-67 Col. 13, ll. 4-24 and 38-61 Col. 14, ll. 21-51 Col. 15, ll. 16-67 Col. 16, ll.17-67 Col. 19, l. 50 – col. 20, l. 6 Col. 21, ll. 18-32 and 43-636 Col. 22, ll.31-50 Col. 23, ll.10 – 33 Col. 23, l. 54 – col. 24, l 9 Col. 24, ll. 25-44 Col. 26, ll. 28 and 34 (phosphate buffer) Col. 26, l. 62 – col. 27, l. 21 Col. 27, ll. 59-65 Col. 28, ll. 1-18 and 37-48 Col. 29, ll. 48-56 In Exhibit A hereof, Plaintiffs reserve the right to introduce and rely on expert testimony from Dr. James E. Polli to support their position and to oppose Defendants' proposed construction, on one or more of the following subjects: background on drug formulations; the definition of a person of ordinary skill in the art; and how one of ordinary skill in the art would understand the term "binary buffer system." Defendants maintain that in making such designation Plaintiffs have failed to comply with the requirements of L. Pat. R. 4.2(b), which requires not only an identification of experts who will provide

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		extrinsic evidence in support of claim construction positions, but also a description of the substance of any such expert's proposed testimony. Plaintiffs have failed to provide any such substantive description, and therefore have failed to meet the requirements of L. Pat. R. 4.2(b). As a result, Defendants object to the introduction of expert testimony by Plaintiffs as to claim construction. However, should Plaintiffs introduce the aforementioned expert testimony, Defendants reserve the right to introduce and rely on expert testimony from Dr. Bozena Michniak-Kohn to rebut such expert testimony.
"quick-dissolving tablet" (Claims 7 and 24)	"one that completely dissolves in the mouth in less than about 6 minutes."	Col. 9, ll. 50-58 In Exhibit A hereof, Plaintiffs reserve the right to introduce and rely on expert testimony from Dr. James E. Polli to support their position and to oppose Defendants' proposed construction, on one or more of the following subjects: background on drug formulations; the definition of a person of ordinary skill in the art; and how one of ordinary skill in the art would understand the term "quick-dissolving tablet." Defendants maintain that in making such designation Plaintiffs have failed to comply with the requirements of L. Pat. R. 4.2(b), which requires not only an identification of experts who will provide extrinsic evidence in support of claim construction positions, but also a description of the substance of any such expert's proposed testimony. Plaintiffs have failed to provide any such substantive description, and therefore have failed to meet the requirements of L. Pat. R. 4.2(b). As a result, Defendants object to the introduction of expert testimony by Plaintiffs as to claim construction. However, should Plaintiffs introduce the aforementioned expert testimony, Defendants reserve the right to introduce and rely on expert testimony from Dr. Bozena Michniak-Kohn to rebut such expert testimony.

CERTIFICATE OF SERVICE

I hereby certify that on September 19, 2013, I caused a copy of the foregoing AMENDED JOINT CLAIM CONSTRUCTION AND PREHEARING STATEMENT to be served via ECF on the following:

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Dated: September 19, 2013

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